

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**BAYER HEALTHCARE
PHARMACEUTICALS INC.,**

Plaintiff,

v.

**RJ HEALTH SYSTEMS
INTERNATIONAL LLC,**

Defendant.

Civ. No. 15-6952 (KM) (MAH)

OPINION

MCNULTY, U.S.D.J.:

The plaintiff, Bayer Healthcare Pharmaceuticals Inc. ("Bayer"), brings this action against the defendant, RJ Health Systems International LLC ("RJ Health"). Bayer seeks damages for allegedly misleading and fraudulent information provided by RJ Health regarding the reimbursement price for Mirena®, a hormonal intrauterine device ("IUD") used for birth control. The complaint asserts four causes of action: violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110b(a); tortious interference with business relations; and negligent misrepresentation.

Now before the Court is the motion of Defendant RJ Health to dismiss the Complaint for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6). (Dkt. No. 21) For the reasons set forth below, the motion is granted as to Count 4 of the complaint, but otherwise denied.

BACKGROUND

The plaintiff, Bayer, is a pharmaceutical company incorporated in Delaware with its principal place of business in New Jersey. (Compl. [Dkt. No. 1] ¶ 16) Bayer markets and sells Mirena®, a levonorgestrel-releasing intrauterine system which was approved by the Food and Drug Administration

("FDA") in 2000. (*Id.* ¶ 3, 16, 21, 22) Mirena® is used for intrauterine contraception and to treat heavy menstrual bleeding in women who choose an intrauterine device for contraception. (*Id.* ¶ 3, 24) Mirena® is inserted by a doctor and is effective for up to five years. (*Id.*) Mirena® is a single-source drug, *i.e.*, one which does not have generic equivalents.

The defendant, RJ Health, is a Connecticut company which operates a subscription-based website that provides information, such as codes, descriptions, and prices, for drugs. (Compl. ¶¶ 17, 36) RJ Health's customers include insurance companies, physicians, and other payors in the healthcare industry. (*Id.* ¶ 37) The website provides data feeds which are imported into the customers' medical claims payment systems. (*Id.* ¶ 38) The drug prices from RJ Health's website are used to adjudicate reimbursement claims. (*Id.*)

The price listed on RJ Health's portal for a particular drug is based on the lowest wholesale acquisition cost ("WAC") of the single source drug under a certain drug code. (*Id.* ¶ 41) Drug codes are set forth by the Centers for Medicare and Medicaid Services ("CMS"). The code for Mirena® was J7302. Bayer set the WAC for Mirena® at \$810.51 in November of 2014, or \$13.51 per month based on the five-year efficacy life span of the drug. (*Id.* ¶ 28)

In February of 2015, another levonorgestrel-releasing intrauterine system was approved by the FDA under the name Liletta®. (*Id.* ¶ 29) Liletta® was approved as a new product, a single-source drug in its own right and not a generic for Mirena®. (*Id.* ¶ 30) Liletta® is inserted using a procedure distinct from the one used for Mirena®; has been approved only for contraceptive use and not for menstrual bleeding; and is approved for use for up to three years, as opposed to Mirena®'s five. (*Id.* ¶ 8, 32–34) Furthermore, the WAC for Liletta® is \$625, or \$17.36 per month for its three-year efficacy period. (*Id.* ¶ 35) Although not the same drug, Liletta® was nevertheless assigned the same code (J7302) as Mirena®.

Beginning on June 1, 2015, RJ Health listed the code price for Mirena® as \$625. (*Id.* ¶ 40) This, according to Bayer, is incorrect, because the WAC for

Mirena® is actually \$810.51. Listing the code price as \$625 thus allegedly misleads RJ Health's customers. Furthermore, a provider who purchased Mirena® based on its actual WAC of \$810.51 would be reimbursed for only \$625, resulting in a loss to the provider. (*Id.* ¶ 42) Bayer contends that, as a result (1) providers may stop using Mirena®, leading to a loss for Bayer; and (2) Bayer may suffer loss of market share and loss of goodwill when frustrated providers are denied full reimbursement. (*Id.* ¶¶ 43–44) Bayer attempted to mitigate the situation by temporarily discounting Mirena® to match Liletta®'s price, but this, says Bayer, has caused it additional financial loss. (*Id.* ¶ 45)

Bayer filed its complaint on September 18, 2015. (Dkt. No. 1)¹ RJ Health moved to dismiss the complaint on December 18, 2015. (Dkt. No. 21) The motion was fully briefed before the Honorable Katharine S. Hayden. (Dkt. Nos. 23, 27) On January 22, 2016, the case was reassigned to me. (Dkt. No. 32)

LEGAL STANDARD

Defendant has moved to dismiss the Complaint for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6). Rule 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In deciding a Rule 12(b)(6) motion, a court must take the allegations of the complaint as true and draw reasonable inferences in the light most favorable to the plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (traditional “reasonable inferences” principle not undermined by *Twombly*, *see infra*).

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will

¹ On October 29, 2015, after this case was initiated, CMS changed the codes for the two hormonal IUDs, giving each a separate code. These new codes were effective in January 2016.

not so.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Thus, the complaint’s factual allegations must be sufficient to raise a plaintiff’s right to relief above a speculative level, so that a claim is “plausible on its face.” *Id.* at 570; *see also Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). That facial-plausibility standard is met “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While “[t]he plausibility standard is not akin to a ‘probability requirement’ . . . it asks for more than a sheer possibility.” *Iqbal*, 556 U.S. at 678.

DISCUSSION

A. Grounds for Dismissal Common to All Four Counts

RJ Health’s motion to dismiss rests on the fundamental argument that Bayer is incorrect in alleging that RJ Health listed the same price for Mirena® and Liletta®. RJ Health contends that its website provides the drug-specific pricing for each IUD. Bayer, according to RJ Health, just did not click through far enough; the relevant information may be found by clicking on a link on the page to which Bayer cites. That link leads to a separate page that displays the product-specific information. Because RJ Health’s website contains the correct WAC for Mirena® (\$810.51), it is not the case that it has disseminated false or misleading information.

I am not persuaded that this argument, whatever its ultimate factual merit, can support a motion to dismiss. Bayer contends that the utility of RJ Health’s system is that it automatically uploads pricing information to the customers’ computers. The contention that a human, by clicking around, can get to the proper information begs the question of whether the proper information is uploaded to the customer. Does the upload for Mirena® supply the generalized \$625 price for drug code J7302, or the product-specific \$810.51 price for Mirena®? I cannot make such a determination based on the face of the pleading, and therefore I cannot grant the motion to dismiss on this

basis. Factual questions like this are more appropriately addressed with the benefit of discovery.

RJ Health also argues that the complaint should be dismissed because its system provides customers with one price (the lowest price) for all the drugs within a given drug code. It is not RJ Health's fault, they argue, that CMS listed the less expensive Liletta® within the same drug code as the more expensive Mirena®. Again, this is a factual issue ill-suited for resolution on a motion to dismiss.

RJ Health also contends that because CMS has now given each IUD a separate code, Bayer's claims are moot. It is true that a claim for prospective injunctive relief might be moot. Not so Bayer's claims for damages for based on losses predating the promulgation of the new codes remain.

Having disposed of the overarching objections to the Complaint, I turn to the individual claims.

B. Count I - Lanham Act Claim

The first count of the complaint alleges that RJ Health's actions violated the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). The Act imposes civil liability on any person who "uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which ... misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1). To state a claim under the Lanham Act, a plaintiff must demonstrate the following: "1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." *Groupe SEB United States, Inc. v. Euro-*

Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014) (internal citation and quotation omitted).

RJ Health first argues that the Lanham Act claim should be dismissed because Bayer and RJ Health are not “competitors.” The Supreme Court, however, has explained that the Lanham Act should not be read to apply only to actions between direct competitors. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, ___ U.S. ___, 134 S.Ct. 1377, 1392 (2014) (noting that “the direct-competitor test provides a bright-line rule; but it does so at the expense of distorting the statutory language”). Here, although RJ Health is not in direct competition with Bayer, if it is shown that the website misstates the price for Mirena®, this could affect Bayer’s sales. Such allegations are sufficiently plausible to state a claim under the Lanham Act.

RJ Health objects that Bayer has failed to allege falsity because the website elsewhere contained the correct information about Mirena®, but for the reasons noted above, I reject this contention as a basis for dismissal. RJ Health also argues that Bayer failed to allege that anyone has been actually misled, but Bayer is not required to do so; rather, Bayer is required to plead that the misstatements have a tendency to mislead. That has been done here. Finally, RJ Health contends that the Complaint is devoid of any allegations of injury. I disagree. Bayer has alleged that it offered a price-match discount on Mirena® in order to avoid the lost business and loss of goodwill it fears will result from purchasers being reimbursed for a lesser amount than the cost of the drug. This is sufficient to allege an injury.

The motion to dismiss is denied as to Count I, the Lanham Act claim.

C. Count II - CUTPA Claim

Count II sets forth a claim under the Connecticut Unfair Trade Practices Act, C.G.S.A. § 42-110g(a) (“CUTPA”). A plaintiff alleging a CUTPA claim must demonstrate (1) that the defendant engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce, and (2) that the plaintiff suffered an ascertainable loss of money or property as a result. See

Neighborhood Builders, Inc. v. Town of Madison, 986 A.2d 278, 282 (Conn. 2010). RJ Health seeks dismissal of the CUTPA claim because Bayer's allegations of loss relate to only speculative losses and therefore fail to satisfy the second element, an "ascertainable loss."

"The ascertainable loss requirement is a threshold barrier that limits the class of persons who may bring a CUTPA action seeking either actual damages.... Thus, to be entitled to any relief under CUTPA, a plaintiff must first prove that he has suffered an ascertainable loss due to a CUTPA violation."

Neighborhood Builders, 986 A.2d at 282 (citing *Artie's Auto Body, Inc. v. Hartford Fire Ins. Co.*, 947 A.2d 320, 329–30 (Conn. 2008)). "An ascertainable loss is a loss that is capable of being discovered, observed or established. The term loss ... has been held synonymous with deprivation, detriment and injury. To establish an ascertainable loss, a plaintiff is not required to prove actual damages of a specific dollar amount." *Artie's Auto Body, Inc.*, 947 A.2d at 330 (citations and internal quotation marks omitted). The loss must be measurable, but a plaintiff need not plead a specific, precise amount. *See id.*

The loss alleged by Bayer is within the realm of the measurable, even if Bayer did not provide a specific dollar amount. That is enough to place within the class of persons eligible to sue under CUTPA. Bayer has alleged that, because RJ Health has listed the lowest WAC for the code that contains Mirena® and Liletta® at \$625, Bayer has discounted its price for Mirena® to match that of Liletta®'s. (Compl. ¶ 45) Bayer has characterized the resulting multimillion dollar loss as "likely," but that does not relegate it to the realm of the speculative. Discovery will easily uncover the dates when Bayer implemented the discount, the number of providers to whom the discount was extended, and the number of units of Mirena® sold during that time to those providers. Thus, an actual dollar figure can be easily ascertained. Bayer's other categories of losses, such as lost market-share and loss of goodwill, are also quantifiable with the benefit of discovery, and are therefore also ascertainable, if not ascertained.

On October 29, 2015, CMS announced new codes, one for Mirena® and one for Liletta®, effective January 2016. Thus, the time frame of any damages to Bayer is finite: between June 1, 2015, when RJ Health began listing \$625 for both drugs, until the date when the new codes went into effect. Accordingly, I find that Bayer has sufficiently pled ascertainable loss.

The motion to dismiss is denied as to Count II, the CUTPA claim.

D. Count III - Tortious Interference Claim

Count III alleges tortious interference with business relationships. The elements for such a claim under Connecticut and New Jersey law are similar. Under Connecticut law, a claim for tortious interference with business expectancies requires the following elements: "(1) a business relationship between the plaintiff and another party; (2) the defendant's intentional interference with the business relationship while knowing of the relationship; and (3) as a result of the interference, the plaintiff suffers actual loss." *Hi-Ho Tower, Inc. v. Com-Tronics, Inc.*, 761 A.2d 1268, 1273 (Conn. 2000). Similarly, under New Jersey law, a claimant alleging tortious interference with must demonstrate: "(1) that plaintiff had a reasonable expectation of an economic benefit or advantage; (2) that defendant knew of plaintiff's expectancy; (3) that defendant wrongfully and intentionally interfered with this expectancy; (4) a reasonable probability that but for defendant's wrongful interference, plaintiff would have realized the economic benefit; and (5) that plaintiff was injured as a result of defendant's conduct." *Carpet Grp. Int'l v. Oriental Rug Importers Ass'n, Inc.*, 256 F. Supp. 2d 249, 288 (D.N.J. 2003) (citing *Printing Mart-Morristown v. Sharp Elecs. Corp.*, 563 A.2d 31, 37 (N.J. 1989), and *Fineman v. Armstrong Ward Industries, Inc.*, 980 F.2d 171, 186 (3d Cir. 1992)). Where the claimant alleges tortious interference with prospective contractual relations, the requirements are identical except that the claimant must demonstrate a "reasonable probability" of a contract. See *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1015 (3d Cir. 1994).

Those elements are sufficiently alleged factually. The Complaint pleads that Bayer has been manufacturing and selling Mirena® since 2000, and that since its approval by the FDA, Bayer has sold over nine million units of Mirena® in the United States. (Compl. ¶¶ 3, 5) Mirena® is also approved for use for up to five years, such that a patient may need additional units of Mirena® should the patient decide to use the drug again. (*Id.* ¶ 22) The Complaint also alleges that Mirena® is the only FDA-approved IUD for the treatment of heavy menstrual bleeding in women who choose an IUD for contraception. (*Id.* ¶ 24) Although it is true that past sales do not guarantee future ones, the history of sales of Mirena®, the growing popularity of IUDs in the United States, the need for replacement units for women who choose to continue using Mirena®, and the demand for Mirena® to address heavy menstrual bleeding in women choosing IUDs make it reasonable for Bayer to expect future sales. Such a reasonable expectation is sufficient to satisfy pleading requirements.

Bayer has also sufficiently pled that RJ Health knew of Bayer's business relationships with purchasers of Mirena®. Mirena® is one of the drugs for which code and pricing information can be found on RJ Health's website. The entire purpose of RJ Health's website is to provide certain information to its customers for use in their claims reimbursement processes. (Compl. ¶¶ 36, 37, 38) The existence of the relationship between the drug manufacturer and its customers is the very foundation of RJ Health's business model.

¹ As to the third element, I find that Bayer has sufficiently pled that RJ Health acted intentionally and with a wrongful motive. The Complaint alleges that RJ Health contacted Bayer on April 22, 2015, to let Bayer know that RJ Health would be reducing the code price for Mirena® to \$625. (Compl. ¶ 40) The Complaint also alleges that Bayer contacted and met with representatives at RJ Health in an effort to prevent RJ Health from reducing Mirena®'s code price, explaining the likely harmful effect of the reduction. (*Id.* ¶ 11) This is a sufficient allegation that RJ Health reduced the code price for Mirena® even

while knowing that it would have a detrimental effect on Bayer. This of course is not proof of ill intent, but it is a sufficient allegation.

Finally, the Complaint adequately pleads an injury or loss. RJ Health argues that there is no allegation of any actual lost sale. Admittedly, the Complaint spends much of its time alleging the potential for losses, such as the potential that a payor will not be reimbursed the full amount for Mirena® and will switch to Liletta® or another drug, resulting in lost profits, lost market share, and loss of goodwill for Bayer. However, Bayer has also alleged that it had to deeply discount the price of Mirena® to match the lower WAC for Liletta®, at a cost to it of tens of millions of dollars. (Compl. ¶ 45) This injury or loss has already occurred to Bayer, and the amount of the loss is ascertainable as stated above.. Accordingly, I find that Bayer sufficiently pled an injury or loss to support its claim.

The motion to dismiss is denied as to Count III, the tortious interference claim.

E. Count IV - Negligent Misrepresentation Claim

In Count IV, Bayer pleads a claim of negligent misrepresentation. To establish such a claim, a plaintiff must show “[a]n incorrect statement, negligently made and justifiably relied on, which results in economic loss.” *Konover Constr. Corp. v. E. Coast Constr. Servs. Corp.*, 420 F. Supp. 2d 366, 370 (D.N.J. 2006) (quotations omitted). RJ Health seeks dismissal of this claim on the grounds that Bayer cannot plead that it relied on any alleged misrepresentation and because Bayer has failed to allege damages sustained as a result of the misrepresentation. Bayer counters that it need not be the party that relied on the misrepresentations; rather, it can recover for damages sustained as a result of reliance by third parties.

I do not reach all of Bayer’s contentions because I find that the Complaint fails to plead actual reliance on the part of the payors. Although the Complaint alleges that payors *would* or *will* only be reimbursed for \$625 versus \$810.51, there are no allegations of this actually having occurred.

For this reason the motion to dismiss is granted as to Count IV, the negligent misrepresentation claim. This dismissal is without prejudice to the filing of an Amended Complaint within thirty days.

;

CONCLUSION

For the reasons set forth above, Defendant's motion to dismiss the complaint is granted as to Count Four, but otherwise denied. An appropriate Order follows.

Dated: June 30, 2016


HON. KEVIN MCNULTY, U.S.D.J.